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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,971	Applicant(s) HUMPHREY, STUART MICHAEL
	Examiner RONALD T. NIEBAUER	Art Unit 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 March 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.
 4a) Of the above claim(s) 3,4,6,8 and 10 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,2,5,7,9 and 11-15 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 23 May 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 02/29/06

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election of Group 1 (claims 1-9,11-15) and the following species:

Alpha-MSH analogue – [Nle⁴,D-Phe⁷]-alpha-MSH

Patient population – Fitzpatrick skin type

Sequence – SEQ ID NO:1

in the reply filed on 3/18/09 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In the instant case, a combination of all of the species were not found in a single prior art reference. In particular, SEQ ID NO:1 of claim 15 was not found in the prior art in the context of the instant claims. In accord with section 803.02 of the MPEP the search was extended to non-elected species. It is noted that the species of claim 15 were not found in the prior art in the context of the instant claims. However, claim 15 is rejected for other reasons. As such, no claims are in allowable form. In accord with section 803.02 of the MPEP the search has been extended and art has been found that obviates the independent claims which are rejected and claims to nonelected species are held withdrawn from consideration.

Even though claim 10 has been amended, claim 10 remains a member of Group 2. Claims 3-4,6,8 read on peptides other than the elected peptide. Since applicant elected Fitzpatrick skin type, claims 12-13 do not expressly read on the elected species. However, since art was

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uncovered in the search for the elected species that obviated species of claims 12-13 such claims are included in the instant examination.

Claim 10 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/18/09.

Claims 3-4,6,8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/18/09.

Claims 1-2,5,7,9,11-15 are under consideration.

Claim Objections

Claims 1,5,7 are objected to because of the following informalities:

Claim 1 refers to the abbreviations MC1R and MSH. These abbreviation should be spelled out the first time they are used in the claims (see the specification page 1).

37 CFR 1.821(d) states: “Where the description or claims of a patent application discuss a sequence that is set forth in the “Sequence Listing” in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by “SEQ ID NO:” in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.” In the instant case, the last 2 sequences in claim 5 are SEQ ID NO:5 and SEQ ID NO:6 respectively. However, the words SEQ ID NO:5 and SEQ ID NO:6 do not appear in the claim.

Claim 5 is objected to for not ending in a period. MPEP § 608.01(m) states that, “Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995).”

The 21st compound of claim 7 recites 'LYS'. Since all of the other amino acid abbreviations are of the form in which the first letter is capitalized and the other two letters are lower case, 'LYS' should appear as 'Lys'.

Claim 7 uses commas to separate some of the compounds (see page 4), but other compounds (see the bottom of page 5) are not separated by commas. The claims should be of a consistent format.

Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities:

37 CFR 1.821(d) states: “Where the description or claims of a patent application discuss a sequence that is set forth in the “Sequence Listing” in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by “SEQ ID NO: ” in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.” In the instant case, the sequences of page 7 lines 4-5 are SEQ ID NO:5 and SEQ ID NO:6 respectively. However, the words SEQ ID NO:5 and SEQ ID NO:6 do not appear with the sequences.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2,5,7,9,11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims 12-15 refer to an alpha-MSH analogue. It is noted that the specification (page 5 lines 19-25) defines the term analogue in terms of a derivative. However, the scope of 'derivatives' is unclear. There is not a standard art-recognized definition of derivative. As such, it is unclear what structural features, if any, are required by the derivatives. There is more than one reasonable interpretation of what falls within the scope of the claims. For example, it is unclear if any compound which contains a hydrogen (and meets the functional requirements) would be considered a derivative because the hydrogen is a shared element. It is noted that the applicants refer to examples of analogues. However, an exemplification is not the equivalent of an explicit, precise definition.

Claims 12 and 13 recite various variant alleles one of which is Asp194His (D294H). Since the variant refers to position 194 and 294 it is unclear if the variation occurs at the 194th position or at the 294th position or at both positions. As such, there is more than one reasonable interpretation of the claims.

Independent claims 1 and 11 refer to 'the steps of administering'. It is noted that the claims use the plural word 'steps' which implies more than one step. However, claims 1 and 11 only refer to one specific step - administration. It is unclear if the intent is that there are to be

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multiple administration steps or if the intent is that there is some other unnamed step. As such, it appears that the claims are incomplete or involve some type of error. It is noted that dependent claims 2,5,7,9,11-14 do not appear to recite any additional steps, while claim 15 appears to recite the step of identification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that “the inventor invented the claimed invention.” Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (“[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.”). Thus, an applicant complies with the written description requirement “by describing the invention, with all its claimed limitations, not that which makes it obvious,” and by using “such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.” Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.” Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.*, the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and

knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.” MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case are discussed below.

Further, to provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include: a) the scope of the invention; b) actual reduction to practice; c) disclosure of drawings or structural chemical formulas; d) relevant identifying characteristics including complete structure, partial structure, physical and/or chemical properties, and structure/function correlation; e) method of making the claimed compounds; f) level of skill and knowledge in the art; and g) predictability in the art.

In the instant case, claims 1,12-15 are drawn to methods of administering an analogue. Although unclear (see 112 2nd), the term analogue has been given the broadest reasonable interpretation such that any structural similarity is sufficient to be classified as an analogue. Claims 12-13 have been interpreted as being drawn to a variation at the 294th position (see page 2 line 8 of the specification). Claims 1,11 and dependent claims 2,5,7,9,11-14 have been interpreted as being drawn to a single step of administration.

(1) Level of skill and knowledge in the art/predictability in the art:

The level of skill in the art is high. There is unpredictability in predicting functional effects of replacements. It is not within the skill of the art to predict any and all replacements that would result in derivatives in which the resulting compound exhibits agonist activity for the melanocortin-1 receptor.

(2) Scope of the invention/Partial structure/disclosure of drawings:

In the instant case, the claims 1,12-15 are drawn to methods of administering an analogue. Although unclear (see 112 2nd), the term analogue has been given the broadest reasonable interpretation such that any structural similarity is sufficient to be classified as an analogue. Claims 12-13 have been interpreted as being drawn to a variation at the 294th position (see page 2 line 8 of the specification). Claims 1,11 and dependent claims 2,5,7,9,11-14 have been interpreted as being drawn to a single step of administration. In considering the size of the genus, if six of the 13 amino acids of MSH were replaced with any of the 20 naturally occurring amino acids (i.e. derivatives) there are at least 20^6 (i.e. 64000000) different compounds. Further, there are many non-natural amino acids and other chemical compounds that could be considered derivatives. As such, the genus is large.

The specification, for example claims 5 and 7 (which are not included in this rejection) provides examples of analogues. However, the compounds represent a small fraction of the possible variety of compounds in the genus. One of skill in the art would not recognize that applicant was in possession of the claimed genus. There is substantial variability in the genus. Since there are a substantial variety of compounds possible within the genus, the examples do

not constitute a representative number of species and do not sufficiently describe the genus claimed (see Gostelli above).

(3) Physical and/or chemical properties and (4) Functional characteristics:

The analogues are defined to exhibit agonist activity for the melanocorin-1 receptor. However, there is no specific disclosed correlation between structure and function. It is unclear what structural elements are required for the recited function. There are no common attributes or characteristics that identify the agonists. As such, one of skill in the art would not recognize a core structure, common attributes, or features of the agonists. One of skill in the art would not recognize agonists outside of those specifically identified. There is no teaching in the specification regarding what part of the structure can be varied while retaining the ability to be an agonist. In particular, no common core sequence is taught. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus and that there is a lack of the knowledge in the art regarding which amino acids can vary to maintain the function and thus that the applicant was not in possession of the claimed genus.

(5) Method of making the claimed invention/actual reduction to practice:

The specification, for example claims 5 and 7 (which are not included in this rejection) provides examples of analogues and refers to other analogues (page 2 last paragraph). However, such compounds are not representative of the instant genus nor do the compounds provide a specific correlation between structure and function such that one could identify any and all agonists.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) 1,12-15 is/are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are many. Although the claims may recite some functional characteristics, the claims lack written description because there is no specific disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus. While having written description of compounds identified in the specification tables and/or examples, the specification does not provide sufficient descriptive support for the myriad of compounds embraced by the claims.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does “little more than outline[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.”) Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2,5,7,9,11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine et al (JAMA 1991 266(19):2730-2736 as cited in IDS 8/29/06) and Epitan (Epitan 2001 Annual Report 36 pages, accessed from http://www.clinuvel.com.au/resources/pdf/annual_reports/Annual_Report_2001.pdf) and Bastiaens et al (Am J Hum Genet 2001 68(4):884-894 as cited in IDS).

Levine teach the administration of [Nle4,D-Phe7]-alpha-MSH to men with skin type I or II, for example, to induce skin tanning (page 2730). Levine recognize a need to treat those at risk for skin cancer who burn easily and state that a strategy is to produce tanning without sun exposure (page 2730 last paragraph). Levine teach that the [Nle4,D-Phe7]-alpha-MSH peptide has desirable properties including improved potency and stability over alpha-MSH (page 2731 column 1, page 2735 3rd column). Levine conclude (page 2734 3rd column) that those humans who were administered [Nle4,D-Phe7]-alpha-MSH had increased skin pigmentation and that subjects who tan poorly responded to the treatment.

Levine does not expressly teach administration to subjects who have an MC1R variant allele.

Levine recognize a need to treat those at risk for skin cancer who burn easily and state that a strategy is to produce tanning without sun exposure (page 2730 last paragraph). Levine teach the use of [Nle4,D-Phe7]-alpha-MSH (page 2730).

Epitan also recognize a need to treat those at risk for skin cancer and discuss the use of Melanotan (also known as [Nle4,D-Phe7]-alpha-MSH) (actual page 3, listed as page number 01; page 4). Epitan refers to the Levine article (page 4 3rd column) and stated that the results demonstrate that the drug could be used to induce a natural tan in human beings. On page 13 (listed as page 10 11) Epitan teach that studies have shown that an increased skin cancer risk is attributed to individuals with abnormal melanocyte receptors in the skin and studies will determine the individuals whom would most benefit from treatment. Thus one would be motivated to treat specific patients who would benefit from the treatment. Epitan does not expressly list specific abnormal melanocyte receptors.

Bastiaens teach that MC1R gene variants are important independent risk factors for skin cancer (abstract, page 891 2nd column). Bastiaens teach that carriers with two variant alleles were at an increased risk for developing cell carcinoma (abstract, page 892 first column) and Bastiaens mention Asp84Glu, and Asp294His as alleles having the highest relative risks (abstract, see also Table 2 and 4). Bastiaens also recognize that fair skin and red hair are associated with an increased risk of melanoma (page 884). Bastiaens recognize that alpha-MSH has effects on melanocytes (page 885). Bastiaens report a patient population with various skin types including type I and II (Table 1). It is noted that Bastiaens report detecting MC1R gene variants (page 887 2nd column) but does not report the use of the primers as in claim 15 of the instant invention.

Since Levine and Epitan motivate the use of [Nle4,D-Phe7]-alpha-MSH for specific patient populations and Epitan specifically teach human individuals with abnormal melanocyte receptors one would be motivated to administer [Nle4,D-Phe7]-alpha-MSH to humans with abnormal melanocyte receptors. Since Bastiaens teach that MC1R (melanocortin-1 receptor) gene variants are important independent risk factors for skin cancer (abstract, page 891 2nd column) and specifically point to Asp84Glu, and Asp294His as alleles having the highest relative risks (abstract, see also Table 2 and 4) one would be motivated to administer [Nle4,D-Phe7]-alpha-MSH to humans with the Asp84Glu, and Asp294His alleles. One would have a reasonable expectation of success since Levine conclude (page 2734 3rd column) that those humans who were administered [Nle4,D-Phe7]-alpha-MSH had increased skin pigmentation and that subjects who tan poorly responded to the treatment.

Since the references obviate the administration of [Nle4,D-Phe7]-alpha-MSH the compound limitations of claims 1-2,5,7,9,11 are met. Since the references obviate the administration to those with MC1R variant alleles especially Asp84Glu, and Asp294His as well as those with fair skin including types I and II the patient population of claims 1,11-14 are met. Since the references motivate the use of [Nle4,D-Phe7]-alpha-MSH to induce skin pigmentation one would be motivated to administer an effective amount as recited in the instant claims.

In the instant case, the references recognize a need to treat those at risk for skin cancer who burn easily, for example. Levine and Epitan set forth the use of a particular compound to achieve such goal. Epitan motivates the administration to a specific sub-population of patients (those with abnormal melanocyte receptors) and Bastiaens teach facts about abnormal melanocyte receptors and the related cancer risk. From the teachings of the references, it is

apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Although unclear (see 112 2nd), the term analogue has been given the broadest reasonable interpretation such that any structural similarity is sufficient to be classified as an analogue. Claims 12-13 have been interpreted as being drawn to a variation at the 294th position (see page 2 line 8 of the specification). Claims 1,11 and dependent claims 2,5,7,9,11-14 have been interpreted as being drawn to a single step of administration.

Related Prior Art

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Dorr et al (Photocem Photobiol 2000 72(4):526-532 as cited in IDS) teach administration of [Nle4,D-Phe7]-alpha-MSH to human patients (abstract). Dorr suggests that specific individuals (Type I skin for example) should also be tested (page 530-531 connecting paragraph).

Dorr et al WO 0372027 (as cited in IDS) teach the use of Melanotan-1 (i.e. [Nle4,D-Phe7]-alpha-MSH) and teach that there may be important implications for individuals with MC1R variant alleles (page 19-20 connecting paragraph).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD T. NIEBAUER whose telephone number is (571)270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654

/Ronald T Nicbauer/
Examiner, Art Unit 1654

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